



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/523,243

10/12/2005

Michael Brock

Muller-47

6495

39703

7590

03/24/2008

C. JAMES BUSHMAN
5718 WESTHEIMER
SUITE 1800
HOUSTON, TX 77057

EXAMINER

SOROUGH, LAYLA

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

03/24/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/523,243	Applicant(s) BROCK ET AL.	
	Examiner LAYLA SOROUGH	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 18-26 is/are pending in the application.
- 4a) Of the above claim(s) 18-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 25-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/11/05; 4/28/05; 12/27/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election of Group I, claims 1-12 and 25-26, with traverse is acknowledged. Because the applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP 818.03 (a)). The requirement is still deemed proper and is therefore made **FINAL**. Applicant's arguments regarding the species election is persuasive and the species restriction of record is herewith withdrawn.

Claims 1-12 and 18-26 are pending.

Claims 18-24 are withdrawn from further consideration pursuant to 37 C.F.R. 1.142(b), as being drawn to non-elected subject matter. The claims corresponding to the elected subject matter are 1-12 and 25-26 are herein acted on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what applicant means by "and optionally also" of claim 7. Applicants have not proceeded to define what is optional.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass.

A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 12 provides for the use of the microemulsion according to any one of claims 1 or 2 in cosmetic applications and/or the production of medicinal product for medicinal dermatologic applications, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 12 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

Art Unit: 1617

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12 and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brock et al. ((IDS) WO 00/47166 – English equivalent US Applic. No. 09/890696) in view of Hasegawa (JP 06234628A), Domsch et al. (DE 10058328A1) and Ansmann et al. (US 6365168 B1).

Brock et al. teaches a medicinal-dermatologic microemulsion comprising (A) 0.5 to 70 % by weight of alkanolammonium salts of the alkylsulfates and/or alkylpolyalkyleneglycoethersulfates having the following structure $R^1-O-(C_pH_{2p}O)_m-SO_3^-HN^+R^2R^3R^4$, where R^1 = is a C_8 - to C_{20} -hydrocarbon residue, p = is an integer from 2 to 5, where p can be different for each m , R^2 = H, a C_1 - to C_6 -alkyl, or a C_2 - to C_4 -hydroxyalkyl, R^3 = H, a C_1 - to C_6 -alkyl, or a C_2 - to C_4 -hydroxyalkyl, R^4 = a C_2 - to C_4 -hydroxyalkyl, preferably a C_3 -hydroxypropyl, and m = is an integer from 0 to 7, (B) 20 to 95 % by weight of water, (C) 0.1 to 20 % by weight of one or more oil component(s), and (D) 0.1 to 20 % by weight, preferably 0.1 to 15 % by weight of one or more mono- or polyhydric, preferably mono-, di-, or trihydric C_2 - to C_4 - alcohol(s), preferably C_2 - to C_6 -alcohol(s) (p.5 and 6), as recited in claims 1 in part and 12. Further, Brock et al. teaches “The compositions according to the present invention most preferably contain alkanolammonium salts of the alkyl- sulfates and/or alkylpolyalkyleneglycoethersulfates of the aforesaid general structure. Preferably, they have independently of one another the following radicals: R^1 = C_{12} - to C_{16} -alkyl, the alkyl residue being linear and saturated, p = 2 or 3, where p can be different for each m , R^2 = H or hydroxyisopropyl, R^3 = H or hydroxyisopropyl, R^4 = hydroxyisopropyl, and m = 0, 1, or 2 (p 8 lines 10-16),”

Art Unit: 1617

as recited in claim 5 The microemulsions contain : (A) 2 to 60 % by weight, preferably 20 to 40 % by weight, (B) 30 to 80 % by weight, preferably 40 to 60 % by weight, (C) 0.5 to 15 % by weight, preferably 4 to 10 % by weight, (D) 0.1 to 9 % by weight, preferably 0.5 to 9 % by weight, (E) 0 to 20 % by weight, preferably 3 to 15 % by weight of additional surfactants, (F) 0 to 20 % by weight, preferably 1 to 12 % by weight of electrolytes, and (G) 0 to 10 % by weight, preferably 0.1 to 8 % by weight of additives (p. 6 and 7), as recited in claims 6 and 7. Brock et al. teaches "as an additional surfactant is a triglyceride alkoxylated with ethyleneoxide and/or propylene- oxide and subsequently esterified, wholly or in part, with C6- to C22-fatty acids (p. 7)," as recited in claim 8. The oil components of the present invention are advantageously chosen from the group of lecithins and the group of mono-, di-, and/or triglycerides of saturated and/or unsaturated, branched and/or linear alkylcarboxylic acids having chain lengths of from 8 to 24, particularly from 12 to 18 carbon atoms. The fatty acid triglycerides can advantageously be synthetic, semisynthetic, or natural oils, such as soya oil, castor oil, olive oil, safflower oil, wheatgerm oil, grapeseed oil, sunflower oil, peanut oil, almond oil, palm oil, coconut oil, thistle oil, evening primrose oil, rape oil, etc. The oil component can furthermore comprise vaseline, paraffin oil, and polyolefins. Moreover, the oil components according to the present invention can advantageously be selected from the group of esters of saturated and/or unsaturated, branched and/or linear alkylcarboxylic acids having chain lengths of from 3 to 30 carbon atoms and of saturated and/or unsaturated, branched and/or linear alcohols having chain lengths of from 3 to 30 carbon atoms. It is furthermore advantageous to select the oil components

Art Unit: 1617

from the group of esters of aromatic carboxylic acids and saturated and/or unsaturated, branched and/or linear alcohols having chain lengths of from 3 to 30 carbon atoms, which ester oils can advantageously be chosen from the group of isopropyl myristate, isopropyl palmitate, isopropyl stearate, isopropyl oleate, n-butyl stearate, n-hexyl laurate, n-decyl oleate, isooctylstearate, isononylstearate, isononylisononanoate, 2-ethylhexylpalmitate, 2-ethylhexyllaurate, 2-hexyldecyl- stearate, 2-octyldodecylpalmitate, oleyl oleate, oleyl erucate, erucyl oleate, erucyl erucate, and synthetic, semisynthetic, and natural mixtures of such esters, e.g. jojoba oil.

Furthermore, the oil component can advantageously be selected from the group of branched and linear hydro\ carbons and hydrocarbon waxes and silicone oils. Any mixtures of the aforesaid oil components are also advantageous within the meaning of the present invention (p. 8 and 9),” as recited in claim 9. The microemulsion is stable, optically transparent and the average particle size is preferably less than 100 nm (p. 7), as recited in claim 10. The reference teaches “preferably, the microemulsions of the invention contain no or at most only small quantities (less than 1.5 % by weight) of polyhydroxyfatty acid amides (so-called glucamides). Moreover, it is preferable that the composition of the invention contains no or at most only small amounts (less than 0.5 % by weight) of anionic surfactants of the sulfonate type (p. 11),” as recited in claim 11. The additives used by Brock et al. include vitamins and preservatives.

The reference fails to specifically teach the additive UV filters such as octocrylenes, 4-methoxycinnamic acid-2-ethylhexyl ester, 2-phenylbenzimidazol-5-sulfonic acid, 2-hydroxy-4-methoxybenzophenone sulfonic acid, and 4-

Art Unit: 1617

bis(polyethoxy)paraminobenzoic acid polyethoxyethyl ester, and mixtures thereof and anti-dandruff agents.

Hasegawa is solely used to show that nicotinic acid (3-aminopyridine niacinamide-vitamin) and its derivatives are useful in treating dandruff (or are anti-dandruff agents) (Abstract).

Domsch et al. is solely used to show that climbazol (1-(4-chlorophenoxy-1-(1-H-imidazol-1-yl)-3,3,-di-methyl-2-butanone) is a preservative and an antidandruff agent (Abstract).

Ansmann et al. is solely used to show that climbazol is an antidandruff agent and that “secondary light filters of the antioxidant type, which interrupt the photochemical reaction chain initiated when UV radiation penetrates into the skin” are useful in topical cosmetics. “Typical examples of these secondary light filters are Superoxid-Dismutase, Tocopherols (vitamin E) and ascorbic acid (vitamin C).”

Ansmann et al. further teaches UV filters are organic compounds which are capable of absorbing ultraviolet rays and of releasing the energy absorbed in the form of longer wave radiation, for example heat. Typical examples are 4-aminobenzoic acid and esters and derivatives thereof (for example 2-ethylhexyl-p-dimethylaminobenzoate or p-dimethylaminobenzoic acid octyl ester), methoxycinnamic acid and derivatives thereof (for example 4-methoxycinnamic acid-2-ethylhexyl ester), benzophenones (for example oxybenzone, 2-hydroxy-4-methoxybenzophenone), dibenzoyl methanes, salicylate esters, 2-phenyl benzimidazole-5-sulfonic acid, 1-(4-tert.butylphenyl)-3-(4'-methoxyphenyl)-propane-1,3-dione, 3-(4'-methyl)-benzylidenebornan-2-one, methyl-

Art Unit: 1617

benzylidene camphor and the like. Other suitable UV filters are finely disperse metal oxides and salts, for example titanium dioxide, zinc oxide, iron oxide, aluminium oxide, cerium oxide, zirconium oxide, silicates (talcum) and barium sulfate.

It would have been obvious to one of ordinary skill in the art to incorporate the UV filters and antidandruff substances into the composition of Brock et al. The motivation to make such an incorporation is because Brock et al. teaches the use of additives such as preservatives, antioxidants, and vitamins (which are also UV filters and antidandruff agents as taught by Hasegawa, Domsch et al., and Ansmann et al. references) in the microemulsion. Hence a skilled artisan would have reasonable expectation of successfully producing a stable medicinal-dermatologic microemulsion by incorporating the UV filter and antidandruff agents.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Art Unit: 1617

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1,5-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-17 and 20 of copending Application No. 09890696. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application are drawn to microemulsion comprising (A) 0.5 to 70 % by weight of alkanolammonium salts of the alkylsulfates and/or alkylpoly-alkyleneglycoethersulfates having the following structure $R^1-O-(C_pH_{2p}O)_m-SO_3-HN^+R^2R^3R^4$, where R^1 = is a C_8 - to C_{20} -hydrocarbon residue, p = is an integer from 2 to 5, where p can be different for each m , R^2 = H, a C_1 - to C_6 -alkyl, or a C_2 - to C_4 - hydroxyalkyl, R^3 = H, a C_1 - to C_6 -alkyl, or a C_2 - to C_4 - hydroxyalkyl, R^4 = a C_2 - to C_4 -hydroxyalkyl, preferably a C3-hydroxypropyl, and m = is an integer from 0 to 7, (B) 20 to 95 % by weight of water, (C) 0.1 to 20 % by weight of one or more oil component(s), and (D) 0.1 to 20 % by weight, preferably 0.1 to 15 % by weight of one or more mono- or polyhydric, preferably mono-, di-, or trihydric C_2 - to C_4 - alcohol(s), preferably C_2 - to C_6 -alcohol(s) (p.5 and 6), as recited in claims 1 in part and 12. Further, Brock et al. teaches "The compositions according to the present invention most preferably contain alkanolammonium salts of the alkyl- sulfates and/or alkylpolyalkyleneglycoethersulfates of the aforesaid general structure. Preferably, they have independently of one another the following radicals: R^1 = C_{12} - to C_{16} -alkyl, the alkyl residue being linear and saturated, p = 2 or 3, where p can be different for each m , R^2 = H or hydroxyisopropyl, R^3 = H or hydroxyisopropyl, R^4 = hydroxyisopropyl, and m = 0, 1, or 2 (p 8 lines 10-16)," as recited in claim 5 The microemulsions contain : (A) 2 to

Art Unit: 1617

60 % by weight, preferably 20 to 40 % by weight, (B) 30 to 80 % by weight, preferably 40 to 60 % by weight, (C) 0.5 to 15 % by weight, preferably 4 to 10 % by weight, (D) 0.1 to 9 % by weight, preferably 0.5 to 9 % by weight, (E) 0 to 20 % by weight, preferably 3 to 15 % by weight of additional surfactants, (F) 0 to 20 % by weight, preferably 1 to 12 % by weight of electrolytes, and (G) 0 to 10 % by weight, preferably 0.1 to 8 % by weight of additives whereas the instant claims are drawn to a microemulsion comprising (A) 0.5 to 70 % by weight of alkanolammonium salts of the alkylsulfates and/or alkylpoly-alkyleneglycolethersulfates having the following structure $R^1-O-(C_pH_{2p}O)_m-SO_3-HN^+R^2R^3R^4$, where R^1 = is a C_8 - to C_{20} -hydrocarbon residue, p = is an integer from 2 to 5, where p can be different for each m , R^2 = H, a C_1 - to C_6 -alkyl, or a C_2 - to C_4 -hydroxyalkyl, R^3 = H, a C_1 - to C_6 -alkyl, or a C_2 - to C_4 -hydroxyalkyl, R^4 = a C_2 - to C_4 -hydroxyalkyl, preferably a C_3 -hydroxypropyl, and m = is an integer from 0 to 7, (B) 20 to 95 % by weight of water, (C) 0.1 to 20 % by weight of one or more oil component(s), and (D) 0.1 to 20 % by weight, preferably 0.1 to 15 % by weight of one or more mono- or polyhydric, preferably mono-, di-, or trihydric C_2 - to C_4 - alcohol(s), preferably C_2 - to C_6 -alcohol(s) and additional ingredients of UV filters and anti-dandruff substances.

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate the UV filter and antidandruff agents to the medicinal-dermatologic microemulsion with reasonable expectation of successfully producing a stable medicinal-dermatologic composition.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-5008. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Layla Soroush/

Examiner, Art Unit 1617

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617